PATENT COOPERATION TREATY

PCT

REC'D 19 OCT 2001
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P2000134C	**FOR FURTHER ACTION** See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CN00/00254	International filing date (day/month/year) 30 AUG. 2000(30.08.00)	Priority date *(day/month/year)* 07 SEP. 1999(07.09.99)

International Patent Classification (IPC) or national classification and IPC

IPC7 A61L27/52, A61F2/12

Applicant

CAO, Mengjun

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and /or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ priority
- III ☐ Non-establishment of opinion with regard to novelty ,inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2)with regard to novelty ,inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international opplication.

Date of submission of the demand	Date of completion of this report
30 MAR. 2001(30.03.01)	10 SEP. 2001(10.09.01)
Name and mailing address of the IPEA/CN 6 Xitucheng Rd.. Jimen Bridge, Haidian District, 100088 Beijing, China Facsimile No. 86-10-62019451	Authorized officer QIU, Jiangyu Telephone No.86-10-62093037

Form PCT/IPEA/409(cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CN00/00254

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-4 .as originally filed

pages _____ .filed with the demand

pages _____ ,filed with the letter of _____

☒ the claims:

Nos _____ .as originally file

Nos _____ , as amended (together with any statement)under Article 19

Nos 1-14 ,filed with the demand

Nos _____ .filed with the letter of _____

☒ the drawings:

sheets/fig 1-2 .as originally filed

sheets/fig _____ .filed with the demand

sheets/fig _____ .filed with the letter of _____

☐ the sequence listing part of the description:

pages _____ .as originally filed

pages _____ .filed with the demand

pages _____ ,filed with the letter of _____

2. with regard to the **language** ,all the elements marked above were available or furnished to this Authority in the language in which the international application was filed,unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application(under Rule 48.3(b)).

☐ the banguage of the translation furnished for the purposes of international preliminary examination (under Ruls Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application.the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description,pages _____

☐ the claims Noa. _____

☐ the drawings,sheets/fig _____

5. ☐ This report has been established as if (some of)the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments(Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIM[redacted]Y EXAMINATION REPORT

International application No. PCT/CN00/00254

V. Reasoned statement under Article 35(2)with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims	1-14	YES
	Claims		NO
Inventive step (IS)	Claims	1-14	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. Claims 1-14 meet the criteria set out in PCT Article 33(2)-(4), because the documents cited in the international search report do not disclose or fairly suggest the subject-matter of claim 1 or 7 and the claims appedant therto.

CLAIMS

1.A mammary prosthesis made of polyacrylamide hydrogel, comprising shell 2 which is made of medical high polymer elastic material, and polyacrylamide hydrogel 4 filled in said shell 2.

2.A mammary prosthesis as claimed in claim 1 wherein said medical high polymer elastic material is silicon.

3.A mammary prosthesis as claimed in claim 1 wherein said polyacrylamide hydrogel 4 being prepared by adding 2.5-7grams of polyacrylamide dry powder into every 100ml water.

4.A mammary prosthesis as claimed in claim 1 wherein the weight percentage of said polyacrylamide hydrogel 4 is: 2.5 - 8% acylamide, 0.001 - 3.0% cross-linking agent, 0.001 - 4.00% catalyst, 0.001 - 2.00% accelerator, 0.001 - 2.00% facilitator and the other is sterile secondary distilled water.

5.A mammary prosthesis as claimed in claim 4 wherein said cross-linking agent is N , N ´ -methylenebisacrylamide and its homologous compound, or N, N ´ -diallyltartratdiamide, said catalyst is ammonium persulfate or kalium persulfate, said accelerator is sodium

bisulphate or sodium metasulphite, said facilitators comprise triethanolamide, triethlamine or their N, N ´ ethylenediamine substances which contains substituting groups.

6.A mammary prosthesis as claimed in claim 5 wherein said shell 2 has a round curved surface.

7.A mammary prosthesis made of polyacrylamide hydrogel comprising a shell 2 that is made of medical high polymer elastic material; wherein said shell 2 is filled with dry powder 3 of polyacrylamide hydrogel whose weight is matched with the volume (ml) of said shell 2,wherein each 100ml volumes of said shell 2 could be filled with 2.5-7 grams of said dry powder, wherein said shell 2 has non-return valve 1.

8. A mammary prosthesis as claimed in claim 7 wherein each 100ml volumes of the shell 2 could be filled with 4 grams of said dry powder 3.

9.A mammary prosthesis as claimed in claim 7 wherein said medical high polymer elastic material is silicone.

10.A mammary prosthesis as claimed in claim 7 wherein said polyacrylamide hydrogel dry powder in weight comprises 2.5 – 8 units

of acrylamide, 0.001 - 3.0 units of cross-linking agent, 0.001 –4 units of catalyst, 0.001 - 2.00 units of accelerator, 0.001 - 2.00 units of facilitator.

11.A mammary prosthesis as claimed in claim 10 wherein said cross-linking agent is N，N ´ -methylenebisacrylamide and its homologous compound, or N，N ´ -diallyltartratdiamide, said catalyst is ammonium persulfate or kalium persulfate, said accelerator is sodium bisulphate or sodium metasulphite, and said facilitators comprise triethanolamide, triethlamine or their N，N ´ ethylenediamine substances which contains substituting groups.

12.A mammary prosthesis as claimed in claim 7 wherein said shell 2 has a round curved surface.

13.A mammary prosthesis as claimed in claim 12 wherein said non-return valve 1 is located in the center of one face of said shell 2.

专 利 合 作 条 约

PCT

国际初步审查报告

(PCT 条约 36 和细则 70)

申请人或代理人的档案号 P2000134C	关于后续行为 参见"传送国际初步审查报告的通知"(PCT/IPEA/416 表)	
国际申请号 PCT/CN00/00254	国际申请日 *(日/月/年)* 30.8 月 2000(30.08.00)	优先权日 *(日/月/年)* 07.9 月 1999(07.09.99)
国际专利分类(IPC)或者国家分类和 IPC 两种分类 IPC7 A61L27/52, A61F2/12		
申请人 曹孟君		

1. 本国际初步审查单位已作出国际初步审查报告并依照条约第 36 条将其传送给申请人。

2. 本报告共计 3 页，包括扉页。

   ☒ 本报告还有附件，即修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页，和/或对本国际初步审查单位所作出的更正页(见 PCT 细则 70.16 和行政规程 607)。

   这些附件共计 2 页

3. 本报告包括关于下列各项的内容：

   I ☒ 报告的基础

   II ☐ 优先权

   III ☐ 不作出关于新颖性、创造性和工业实用性的意见

   IV ☐ 缺乏发明的单一性

   V ☒ 按条约 35(2)关于新颖性、创造性或工业实用性的推断性意见；支持这种意见的引证和解释

   VI ☐ 引用的某些文件

   VII ☐ 国际申请中的某些缺陷

   VIII ☐ 对国际申请的某些意见

提交要求书的日期 30.3 月 2001(30.03.01)	完成本报告的日期 10.9 月 2001(10.09.01)
国际初步审查单位名称和地址 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号： 86-10-62019451	受权官员 邱绛雯 电话号码： 86-10-62093037

国际[redacted]审查报告

国际申请号
[redacted] PCT/CN00/00254

I. 报告的基础

1. 关于国际申请中各个部分：*

☐ 原始提交的国际申请。

☒ 说明书， 第 1 － 4 页，按 原始提交的，
第 _____ 页，随 要求书提交的，
第 _____ 页，随 _____ 的信件提交的。

☒ 权利要求， 第 _____ 页，原 始提交的，
第 _____ 页，按 条约第 19 条修改的(附有说明)，
第 1 － 14 项，随 要求书提交的。
第 _____ 页，随 _____ 的信件提交的。

☒ 附图， 第 1-2 页，原始提交的。
第 _____ 页，随要求书提交的，
第 _____ 页，随 _____ 的信件提交的。

☐ 说明书中的序列表部分
第 _____ 页，原始要求提交的，
第 _____ 页，随要求书提交的，
第 _____ 页，随 _____ 的信件提交的。

2. 关于所使用的语言，除本项下另有说明外，本国际初步审查单位所获得的或者已向本国际初步审查单位提交的上述所有部分，所使用的语言均为提交本国际申请时所使用的语言。
本国际初步审查单位所获得的或向本国际初步审查单位提交的这些部分所使用的语言是 _____，这种语言是

☐ 为了国际检索而提交的译本所使用的语言（细则 23.1 （ b ））。
☐ 本国际申请公布时所使用的语言（细则 48.3 （ b ））。
☐ 为了国际初步审查而提交的译本所使用的语言（细则 55.2 和/或 55.3 ）。

3. 关于本国际申请中所公开的任何**核甙酸和/或氨基酸的序列**，本国际初步审查是根据下面的序列表进行的：

☐ 国际申请中所包含的书写形式的序列表 。
☐ 与国际申请同时提交的计算机可读形式的序列表。
☐ 后来以书写形式向本国际初步审查单位提交的序列表。
☐ 后来以计算机可读的形式向本国际初步审查单位提交的序列表。
☐ 已提交了关于后来提交的书写形式的序列表没有超出原始提交的国际申请所公开的范围的说明。
☐ 已提交了关于以计算机可读的形式记载的信息是与书写形式的序列表相同的说明。

4. 修改删除了以下内容的：

☐ 说明书， 第 _____ 页
☐ 权利要求， 第 _____ 项
☐ 附图， 第 _____ 页，图 _____

5. ☐ 由于（某些）修改被认为超出了原始公开的范围，如补充栏所示，因此本报告是按照如同没有修改的情况作出的(细则 70.2(c))。**

* 按照条约第 14 条答复通知时向受理局提交的替换页，在本报告中被称为“原始提交的”，这些替换页不作为本报告的附件，因为它们没有包含修改（细则 70.16 和 70.17 ）。

** 任何包含这种修改的替换页，都必须在第 1 项中指明，并作为本报告的附件。

V. 按条约 35 条(2)关于新颖性、创造性或工业实用性的推断性意见；支持这种意见的引证和解释

1. 意见

新颖性(N)	权利要求	1 — 14	是
	权利要求		否
创造性(IS)	权利要求	1 — 14	是
	权利要求		否
工业实用性(IA)	权利要求	1 — 14	是
	权利要求		否

2. 引征和解释（细则 70.7 ）

权利要求 1 至 14 符合 PCT 条约第 33 条第 2 至 4 款的规定，因为国际检索报告中引证的对比文件均没有公开权利要求 1 或 7 以及它们的从属权利要求所要保护的技术方案，并且也没有给出相关的技术启示。

权利要求

1、一种聚丙烯酰胺水凝胶乳房假体，包括：用聚硅氧烷弹性体制成的壳体 2，充填在所述密封壳体 2 内的聚丙烯酰胺水凝胶 4，所述聚丙烯酰胺水凝胶 4 由 100 毫升水加 2.5-7 克聚丙烯酰胺干粉制备而成，其中，聚丙烯酰胺干粉是将重量百分比 2.5 - 8%的丙烯酰胺、0.001 - 3.0%的交联剂、0.001 - 4.00%的催化剂、0.001 - 2.00%的加速剂、0.001 - 2.00%的促进剂，加水到 100%聚合、洗涤、浸泡、离心脱水、烘干而成。

2、根据权利要求 1 所述的乳房假体，其特征在于,所述交联剂为 N，N´- 乙撑双丙烯酰胺及其同系物或 N，N´二烯丙基酒石酸二酰胺。

3、根据权利要求 2 所述的乳房假体，其特征在于,所述催化剂是过硫酸胺或过硫酸钾。

4、根据权利要求 3 所述的乳房假体，其特征在于,所述加速剂可以是亚硫酸氢钠或偏亚硫酸钠。

5、根据权利要求 4 所述的乳房假体，其特征在于,所述促进剂包括三乙醇胺或三乙胺及其含取代基的 N，N´乙二胺类。

6、根据权利要求 5 所述的乳房假体，其特征在于其中，所述壳体 2 有一个球形曲面。

7、一种聚丙烯酰胺水凝胶乳房假体，其特征在于，包括用聚硅氧烷弹性体制成的带单向阀 1 的壳体 2，在所述壳体 2 内置入有其

重量（克）与所述壳体 2 容积（毫升）成一定比例的聚丙烯酰胺水凝胶干粉 3，所述水凝胶干粉 3 重量（克）与所述壳体 2 容积（毫升）的一定比例是每 100 毫升容积 2.5-7 克干粉，所述聚丙烯酰胺干粉是将重量百分比 2.5 - 8%的丙烯酰胺、0.001 - 3.0%的交联剂、0.001 - 4.00%的催化剂、0.001 - 2.00%的加速剂、0.001 - 2.00%的促进剂，加水到 100%聚合、洗涤、浸泡、离心脱水、烘干而成。

8、根据权利要求 7 所述的乳房假体，其特征在于，所述水凝胶干粉 3 重量（克）与所述壳体 2 容积（毫升）的一定比例是 100 毫升：4 克。

9、根据权利要求 8 所述的乳房假体，其特征在于,所述交联剂为 N，N´- 乙撑双丙烯酰胺及其同系物或 N，N´二烯丙基酒石酸二酰胺。

10、根据权利要求 9 所述的乳房假体，其特征在于,所述催化剂是过硫酸胺或过硫酸钾。

11、根据权利要求 10 所述的乳房假体，其特征在于,所述加速剂是亚硫酸氢钠或偏亚硫酸钠。

12、根据权利要求 11 所述的乳房假体，其特征在于,所述促进剂包括三乙醇胺或三乙胺及其含取代基的 N，N´乙二胺类。

13、根据权利要求 7-12 所述的乳房假体，其特征在于，所述壳体 2 有一个球形曲面。

14、根据权利要求 7-12 所述的乳房假体，其特征在于，所述单向阀门 1 设置在所述圆形袋壳体 2 一面的中心位置处。